K954523

THERMOSCAN INC.

510(K) SUMMARY

DEC 10 1996

Submitter's Name:	Thermoscan Inc.
Address:	10421 Pacific Center Court San Diego, CA 92121
Phone:	(619) 550-2100
Contact:	Frances E. Harrison
Date of Summary:	December 9, 1996
Name of Device:	Braun ThermoScan Thermometer, Model IR-6000
Predicate Device:	ThermoScan Instant Thermometer, Model IR-2000 ThermoScan Instant Thermometer, Model IR-4000
Device Description:	The Braun ThermoScan Thermometer, Model IR-6000 is a hand held instrument that measures temperature through the opening of the auditory canal. Operation is based on measuring the natural thermal radiation emitted from the Tympanic membrane and adjacent surfaces
Intended Use:	The Braun ThermoScan Thermometer, Model IR-6000 is intended for the intermittent measurement and monitoring of human body temperature in the home. It is intended for use on people of all ages.
Technological Characteristics:	The Braun ThermoScan Thermometers, Model IR-6000, IR-2000 and IR-4000 have the same general design and incorporate similar technologies, materials and components. The primary function of the Braun ThermoScan Thermometer, Model IR-6000 is the same asThermoScan Instant Thermometer, Models IR-2000 and IR-4000 for the measurement of body temperature and raise no new questions of safety and effectiveness. ThermoScan Inc. concludes that the Braun ThermoScan Thermometer, Model IR-6000 is substantially equivalent to the ThermoScan IR-2000 and ThermoScan IR-4000.

PRODUCT SPECIFICATIONS:

Model Number	HM3, HM3P
Technical Characteristics	
Displayed temperature range	93.2-108°F (34-42.2°C)
Operating ambient temperature range	61-104°F (16.1-40°C)
Display resolution	0.1°F or C
Temperature scales (user selectable)	°F or °C
Operating relative humidity (max)	80%
Long term storage ranges	
Temperature	-4 to 122°F (-20 to 50°C)
Humidity (max)	95% noncondensing
Display modes	EAR (The displayed EAR temperature is the actual measured ear canal temperature plus a mathematical adjustment to approximate the familiar oral range. However, this is not necessarily the same as an oral temperature measured at the same time.)
Weight (without batteries)	3.5 oz (100g)
Memory recall	One previous temperature

Accuracy characteristics*		
Applicable patient ages	All ages	
Laboratory error (max)		
Patient temperature range	Error °F	Error °C
98.0 to 102.0°F (37.0 to 39.0°C)	±0.2	±0.1
96.4 to<98.0°F (35.8 to<37.0°C)	±0.3	±0.2
>102.0 to 106.0°F (>39.0 to 41.0°C)		
<96.4°F (35.8°C or>106.0°F (41.0°C)	±0.5	±0.3

*Accuracy is determined under laboratory conditions in calibrate mode with a typical lens filter installed. See ASTM Standard *"Electronic Thermometer for Intermittent Determination of Patient Temperature"* E1112-86, available from ASTM, 100 Barr Harbor Dr., West Conshoken, PA 19428-2959. Tel (610) 832-9285. Consult company for calibrate mode.

The Braun ThermoScan Thermometer has been proven to be safe. It meets the laboratory accuracy requirement specified in ASTM Standard E1112 as it pertains to infrared thermometers.

SUMMARY OF TESTING:

Non-Clinical Results

Accuracy Test	Passed
Consistency Test	Passed
Operating Life Test	Passed
Lens Filter Detect Switch Operating Life Test	Passed
Cleaning Test	Passed
Acoustic Noise Test	Passed
Altitude Test	Passed
Electrical Short Heat Measurement Test	Passed

Product performance specifications, features and software were validated.

Clinical Results

A comparison study and clinical repeatability testing was performed on the following four age groups; 0-3 yrs, 4-10 yrs, 11-65 yrs, and >65 yrs. The comparison study demonstrated that the Braun ThermoScan Thermometer, Model IR-6000 measured ear temperature equivalently to both the IR-2000 and IR-4000 in all age groups. The clinical repeatability for each age group met ASTM standards.